DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

SEP 17 1999

Mr. Robert A. Dormer
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005

RE: 97A-0534/AP1

Dear Mr. Dormer,

This is in response to your petition dated December 24, 1997, concerning the responsibilities of manufacturers of diagnostic x-ray and computed tomography components and systems, to provide information to users, assemblers, and others under 21 Code of Federal Regulations (CFR) §§ 1020.30(g) and (h), and 1020.33(c) (collectively, the disclosure rules). I apologize for the delay in our response.

Your petition raises issues that are of general concern to manufacturers and assemblers, including the types of software and other information covered by the regulations, and the meaning of "cost" as used in the disclosure rules. In response to your petition and because of the relevance of these issues to the entire manufacturing and assembly industries, we are providing guidance on the meaning of assembly, installation, adjustment, and testing materials (AIAT materials or information), and the appropriate factors for manufacturers to consider in determining the cost of these materials to third parties. Enclosed with this letter is "Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems."

In your petition, you also raise the concern that requiring manufacturers to provide software to third-parties at a cost that is less than the just compensation or fair market value of the software would amount to an unconstitutional government taking under the Fifth Amendment. This letter incorporates our consultation with FDA's Office of Chief Counsel and will respond to your constitutional argument.

Your petition relies on Ruckelshaus v. Monsanto, 467 U.S. 986 (1984), to assert an argument under the Takings Clause. In that case, the Court held that a statutory prohibition on certain uses of information created a "reasonable investment-backed expectation," and that governmental interference with that

97A-0534 AP1

expectation was a taking requiring just compensation. Id. at 1004 (1984). In contrast, neither the disclosure rules nor the Radiation Control for Health and Safety Act give rise to a reasonable expectation that the Food and Drug Administration (FDA) will treat AIAT information as protected from disclosure. Ruckelshaus, then, does not support the argument that required disclosure of AIAT information amounts to a taking mandating just compensation.

Rather than imposing restrictions on use of AIAT information, the disclosure rules have, since 1972, put manufacturers on notice of the requirement that they provide informational materials needed for the assembly, installation, adjustment, and testing of products subject to the performance standard to assemblers and others at cost. The informed decision by manufacturers to encode this information in software does not legitimate any expectation that manufacturers could avoid compliance with sections 1020.30(g), 1020.30(h), or 1020.33(c). In requiring that manufacturers provide AIAT information, then, the disclosure rules constitute permissible regulation, rather than takings requiring just compensation.

Your petition also relies on Dolan v. City of Tigard, 114 S. Ct. 2309 (1994) and Nollan v. California Coastal Commission, 483 U.S. 825 (1987) for the argument that the government must make an "individualized determination" that an appropriation of private property has an "essential nexus" to a legitimate interest, see Dolan at 2319; Nollan at 837. These cases establish legal tests for determining when the government may condition a use of private land on the concession of certain private land uses, and are not necessarily relevant to regulation of informational materials.

To the extent Nollan and Dolan do apply to the requirement of the disclosure rules that manufacturers provide AIAT materials, the cases support the constitutionality of the requirement. The provision of information on the safe assembly and installation of radiation-emitting products bears a close nexus to the protection of the health of assemblers and others, as discussed in the legislative history of the Radiation Control for Health and Safety Act of 1968, see, e.g., U.S. Department of Health, Education, and Welfare, Legislative History of the Radiation Control for Health and Safety Act of 1968, p. 1438. Although the requirement applies generally to all AIAT materials, whether a given document, software program, or other instruction is AIAT material is a highly particular determination, one the agency has attempted to clarify in the enclosed guidance document.

I hope this discussion and enclosed guidance for industry are helpful to you. If you have any questions, please contact Mr. Thomas M. Jakub, Diagnostic Devices Branch, Division of Enforcement I, Office of Compliance (HFZ-322), 2098 Gaither Road, Rockville, Maryland 20850, (301) 594-4591.

Sincerely yours,

David W. Feigal, M.D., M.P.H.
Director
Center for Devices and
Radiological Health

Enclosure